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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,498	10/31/2000	Tsuyoshi Tokusumi	50026/025001	9833

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	16

DATE MAILED: 08/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/702,498	Applicant(s) TOKUSUMI ET AL.	
	Examiner Shanon Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10, 15*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

In paper no. 14, applicant amended claims 1-7, 9, and added new claims 10-22. Claims 1-22 are pending. Upon reconsideration, new grounds of rejection are established. The examiner regrets any inconvenience applicant experiences.

Election/Restrictions

Newly submitted claims 19-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to a method of regulating foreign gene expression in a paramyxovirus vector. The claimed method can be practiced with structurally and functionally distinct viruses within the paramyxovirus genus. Also, methods for regulating gene expression in paramyxoviruses can be accomplished by incorporating the virus into different host cells or using different promoters that control the direct expression of the foreign gene.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-18 are under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague for reciting "counting" from the 3'end. Does the counting begin at the first residue of the leader sequence or the coding sequence of the genome?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Conzelmann et al. (EP 0 702 085 A1) for reasons of record.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Conzelmann et al. (US 6,033,886) for reasons of record.

Applicant argues that neither reference of Conzelmann et al. teach each and every limitation of the instant invention. Applicant asserts that neither Conzelmann et al. reference teaches a replicable paramyxovirus vector expressing a foreign gene downstream of a viral gene in the negative genomic RNA strand. In a reference provided by applicant, Conzelmann et al. teaches low efficiency observed for each additional length of the foreign insert in rabies virus.

Applicant concludes that the recovery system of Conzelmann et al. would not be applicable to the instant system. In addition, Applicant states that Conzelmann et al. only describes the expression of a foreign gene in the pseudogene region of a rabies virus, which is not present in paramyxoviruses, such as Sendai viruses. Applicant summarizes the unequivalent distinctions between rhabdoviruses and paramyxoviruses, which are also discussed by Conzelmann et al. in various references provided by applicant. Also, in contrast to Conzelmann et al., the instant invention uses Sendai viruses, which are more advantageous for human use. Applicant also points out that Conzelmann et al. only manipulates rabies viruses and not paramyxoviruses and does not teach whether or not a recombinant paramyxovirus would function normally or be capable of expressing the foreign gene. In addition, applicant asserts that the Conzelmann et al. does not teach how to predict the expression level of Sendai viruses or provide motivation to do so. Applicant states that the instant invention distinguishes over the prior art in that expression of a foreign gene is accomplished when the insert is positioned downstream of the paramyxovirus gene and that expression is dependent upon placement of the foreign gene.

Applicant's arguments as well as a review of the references have been fully considered, but are found to be unpersuasive. Applicant's summary of the distinctions between paramyxoviruses and rhabdoviruses as well as a summary of teachings in prior art is appreciated. However, the teachings of Conzelmann et al. anticipate manipulating both types of viruses in the claims, including paramyxoviruses, which is explicitly recited in the US patent and EP application claims. Also, applicant's opinion of the inapplicability of the recovery system used in Conzelmann et al. does not distinguish the art from the instant invention since a recovery system is not an element in the instant claims. Applicant also discussed the use of Sendai viruses

in the instant claims to distinguish the instant invention from the references. Applicant is again arguing limitations that are not present in instant claims 1-9. Claims 1-9, which are anticipated by Conzelmann et al., do not recite Sendai viruses. Therefore, no distinction over the prior art has been accomplished. Although it is conceded that Conzelmann et al. only exemplifies manipulations in rabies viruses, the references explicitly teach inserting foreign sequences into intergenic regions of paramyxoviruses. Therefore, it is maintained that both Conzelmann et al. references anticipate claims 1-9. Conzelmann et al. teaches a replicating non-segmented negatively stranded RNA virus mutant comprising an insertion in an open reading frame, the pseudogene region, as well as an intergenic region, see claim 1 of both the US patent and the EP application. The intergenic region is the region between coding sequences. Therefore, Conzelmann t al. teaches altering any one of the intergenic regions in a non-segmented negatively stranded RNA virus by insertion. The non-segmented negatively stranded RNA virus is a paramyxovirus, see claim 9 of either reference. In addition, the insertion of sequences into any intergenic region of a paramyxovirus codes for an epitope or a polypeptide of a pathogenic virus, see claim 8 of both references. Therefore, the rejection is maintained for reasons of record.

New grounds of Rejection under 35 USC § 102

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hasan et al. (Journal of General Virology. 1997; 78: 2813-2820).

The claims are drawn to a replicable paramyxovirus, more specifically a Sendai virus encoding a foreign gene downstream of the viral proteins and located between viral proteins.

Hasan et al. teaches a recombinant Sendai virus that expresses the firefly luciferase gene between the N protein and the 5' end of the RNA genome. The recombinant Sendai virus genome is expressed in a DNA expression vector. See Figure 1 on page 2815. Therefore, the teachings of Hasan et al. clearly anticipate instant claims 1-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Conzelmann et al. references in the alternative (both references are cited above).

The claims are drawn to a replicable Sendai virus encoding a foreign gene downstream of the viral proteins and located between viral proteins.

See the teachings of both Conzelmann references above. Neither reference explicitly teaches inserting a foreign gene between the intergenic regions of a Sendai virus. However, both references, in the alternative, teach inserting an expressing foreign genes in any intergenic region of paramyxoviruses. Therefore, since Sendai viruses are paramyxoviruses, selecting this particular virus among all of the paramyxoviruses that are used to practice the invention of Conzelmann et al. would be an obvious alternative to any one of the viruses within the paramyxovirus family to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
August 13, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1600~~ 1600